UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 14, 2017

MEMORANDUM

SUBJECT: Efficacy Review for EPA Reg. No. 10324-214, Maguard 5626;
DP Barcode: D436828
E-Sub #: 14915

FROM: Marcus Rindal
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Mark Perry
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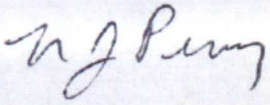

TO: John Hebert / Zebora Johnson, PM 33
Regulatory Management Branch II
Antimicrobials Division (7510P)

APPLICANT: Mason Chemical Company
721 W. Algonquin Road
Arlington Heights, IL 60005

Formulation from the Label:

Active Ingredient	% by wt.
Peroxyacetic Acid	5.9 %
Hydrogen Peroxide	27.3 %
Inert Ingredients:	66.8 %
Total	100.0 %

I BACKGROUND

The registered product, Maguard 5626 (EPA Reg. No. 10324-214), is a dilutable liquid disinfectant (bactericide, fungicide, sporicide, and virucide) sanitizer and deodorizer for use on hard, non-porous, non-food contact surfaces in commercial and institutional environments. The product also may be used in various industrial applications and is a food contact surface sanitizer. The label states that the product is an effective disinfectant in the presence of 400 ppm hard water and 5% blood serum. The label states that the product is an effective food contact surface sanitizer when a solution is prepared in water of up to 500 ppm hardness as $CaCO_3$. Studies were conducted at MicroBioTest Labs, located at 105 Carpenter Drive, Sterling, VA 20164.

This data package contained EPA Form 8570-35 (Data Matrix), a proposed product label (identified as Version 10/26/2016), transmittal document, and two efficacy studies (MRIDs 500061-01 and 500061-02) with Statements of No Data Confidentiality Claims for both studies embedded in the respective MRID.

II USE DIRECTIONS

The product is designed for disinfecting hard, non-porous surfaces, including: appliance exteriors, bathroom fixtures, bed frames, cages, carts, chairs, coolers, counter tops, feeding equipment, floors, furniture, kennel runs, operating tables, racks, shelves, sinks, tables, and walls. In addition, the product is designed for sanitizing pre-cleaned, hard, non-porous surfaces, including: conveyors, drinking utensils, eating utensils, equipment, evaporators, filters, food preparation utensils, pasteurizers, pipelines, saws, slicers, tableware, tanks, and vats. The proposed label indicates that the product may be used on hard, non-porous surfaces, including: glass, glazed porcelain, linoleum, plastic, stainless steel, tile, and vinyl. Directions on the proposed label provide the following information regarding preparation and use of the product:

> As a disinfectant in non-medical facilities: Prepare a use solution by adding 1.5 ounces of the product and 5 gallons of water (a 1:320 dilution). Apply use solution with a brush, cloth, mop, sponge, or mechanical spray device, coarse pump, or trigger spray device thoroughly wetting surfaces as required. Treated surfaces must remain wet for 10 minutes. Rinse or allow to air dry. For heavily soiled areas, a preliminary cleaning is required.
>
> As a disinfectant in institutions: Prepare a use solution by adding 2 ounces of the product and 5 gallons of water (a 1:427 dilution). Apply use solution with a brush, cloth, mop, sponge, or mechanical spray device, coarse pump, or trigger spray device thoroughly wetting surfaces as required. Treated surfaces must remain wet for 10 minutes. Rinse or allow to air dry. For heavily soiled areas, a preliminary cleaning is required.
>
> As a sanitizer: Remove gross food particles. Wash with a detergent solution. Rinse with potable water. Prepare a use solution by adding 1-2 ounces of the product and 6 gallons of water (73-146 ppm active; a 1:768-1:384 dilution). Apply use solution to surfaces, using immersion, coarse spray, or circulation techniques. All surfaces must be exposed for at least 30 seconds. Drain excess solution.

III COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 500061-01, "AOAC Tuberculocidal Activity of Disinfectants," Test Organism: *Mycobacterium bovis* (BCG), for product Maguard 5626, Lot# 50702Z2. Study conducted at MICROBIOTEST Labs by Travis R. Farley. Study completion date – March 31, 2016. Project Number 362-504.

This study was conducted against *Mycobacterium bovis* (BCG), for product Maguard 5626, Lot# 50702Z2. These were tested using MICROBIOTEST Laboratory Protocol No. 362.1.10.23.15 (copy provided). A stock culture of the test organism, on 7H11 agar medium, was transferred into 20 mL tubes of Modified Proskauer-Beck Broth using one or two 1 µL loopfuls of culture and incubated for 21±2 days at 35-37°C in a quiescent position. The test culture was then transferred to a sterile tissue grinder containing 1.00 mL of 0.85% saline + 0.1% tween 80 and was macerated to break up large clumps of the test organism. A 9.0 mL aliquot of Modified Proskauer-Beck Broth was added and, after settling for 10-15 minutes, the upper portion was removed and the suspension was transferred to a sterile vessel. This culture was standardized to 20.0±1% Transmittance (%T) at 650 nm. An aliquot of organic soil (unidentified) was added to the broth culture to yield a 5% organic soil load. Sterile 18 mm x 36 mm glass slide carriers, each in a sterile plastic Petri dish matted with two pieces of filter paper, were each inoculated with 0.01 mL (10.0 µL) of culture using a calibrated pipettor and the inoculum was spread over the surface of the slide (approximately 1 square inch). Each dish was covered and the slides were allowed to dry for 30 minutes at 36°C and at 37% relative humidity (the previous two statements were extracted from the study report but are likely incorrect as nothing else in the report indicates the study was conducted using spray methodology). The carriers were used in the test procedure within 2 hours of drying. The test substance was diluted at a rate of 1:34 (equal to 1-part disinfectant + 34 parts diluent) in 400±2.9% AOAC hard water. Ten inoculated carriers per lot were added to the test substance in the following manner in accordance with *Official Methods of Analysis,* AOAC 965.12. The tubes containing the 10 mL of the test substance (ten tubes per lot of test substance) were allowed to equilibrate to the contact temperature. One contaminated carrier was added to each tube. When lowering the carrier into the disinfectant tubes, neither the carrier nor the transfer hook touched the interior sides of the tube. After the 10-minute contact period each carrier was transferred to a tube containing ten mL of neutralizer in a sequential timed fashion using a sterile hook and all the excess liquid was drained. Each tube was shaken thoroughly and the carriers immediately (within 5- 10 minutes) transferred to a tube containing 20 mL of MPB broth. Contact of the carrier to the interior of the tube during transfer was avoided as much as possible. Once all carriers were transferred to MPB, sequential transfers of 2 mL aliquots from each neutralizer tube was made into corresponding 20 mL M7H9 and 20 mL KM tubes (within 30 minutes). All subculture broths were incubated at 35-37°C under aerobic conditions and were visually examined for growth following 61-day incubations. All test subcultures demonstrated a lack of growth, therefore the subcultures were incubated an additional 30 days and re-examined. Controls included those for purity, sterility, visibility, initial suspension population, neutralization confirmation and carrier population.

2. MRID 500061-02, "AOAC Tuberculocidal Activity of Disinfectants," Test Organism: *Mycobacterium bovis* (BCG), for product Maguard 5626, Lot# 50812Z4. Study conducted at MICROBIOTEST Labs by Travis R. Farley. Study completion date – March 31, 2016. Project Number 362-505.

This study was conducted against *Mycobacterium bovis* (BCG), for product Maguard

5626, Lot# 50812Z4. These were tested using MICROBIOTEST Laboratory Protocol No. 362.2a.10.23.15 (copy provided). A stock culture of the test organism, on 7H11 agar medium, was transferred into 20 mL tubes of Modified Proskauer-Beck Broth using one or two 1 µL loopfuls of culture and incubated for 21±2 days at 35-37°C in a quiescent position. The test culture was then transferred to a sterile tissue grinder containing 1.00 mL of 0.85% saline + 0.1% tween 80 and was macerated to break up large clumps of the test organism. A 9.0 mL aliquot of Modified Proskauer-Beck Broth was added and, after settling for 10-15 minutes, the upper portion was removed and the suspension was transferred to a sterile vessel. This culture was standardized to 20.0±1% Transmittance (%T) at 650 nm. An aliquot of organic soil (unidentified) was added to the broth culture to yield a 5% organic soil load. Sterile 18 mm x 36 mm glass slide carriers, each in a sterile plastic Petri dish matted with two pieces of filter paper, were each inoculated with 0.01 mL (10.0 µL) of culture using a calibrated pipettor and the inoculum was spread over the surface of the slide (approximately 1 square inch). Each dish was covered and the slides were allowed to dry for 30 minutes at 36°C and at 37% relative humidity (the previous two statements were extracted from the study report but are likely incorrect as nothing else in the report indicates the study was conducted using spray methodology). The carriers were used in the test procedure within 2 hours of drying. The test substance was diluted at a rate of 1:34 (equal to 1-part disinfectant + 34 parts diluent) in 400±2.9% AOAC hard water. Ten inoculated carriers per lot were added to the test substance in the following manner in accordance with *Official Methods of Analysis,* AOAC 965.12. The tubes containing the 10 mL of the test substance (ten tubes per lot of test substance) were allowed to equilibrate to the contact temperature. One contaminated carrier was added to each tube. When lowering the carrier into the disinfectant tubes, neither the carrier nor the transfer hook touched the interior sides of the tube. After the 10-minute contact period each carrier was transferred to a tube containing ten mL of neutralizer in a sequential timed fashion using a sterile hook and all the excess liquid was drained. Each tube was shaken thoroughly and the carriers immediately (within 5- 10 minutes) transferred to a tube containing 20 mL of MPB broth. Contact of the carrier to the interior of the tube during transfer was avoided as much as possible. Once all carriers were transferred to MPB, sequential transfers of 2 mL aliquots from each neutralizer tube was made into corresponding 20 mL M7H9 and 20 mL KM tubes (within 30 minutes). All subculture broths were incubated at 35-37°C under aerobic conditions and were visually examined for growth following 61-day incubations. All test subcultures demonstrated a lack of growth, therefore the subcultures were incubated an additional 30 days and re-examined. Controls included those for purity, sterility, visibility, initial suspension population, neutralization confirmation and carrier population.

IV RESULTS

MRID Organism	Subculture Medium	Lot #	No. Exhibiting Growth / Total No. Carriers Tested	Carrier Population (CFU/ Carrier)
10 Minute Exposure Time				
500061-01 *Mycobacterium bovis* (BCG)	Modified Proskauer-Beck Broth	50702Z2	0/10	7.5×10^4
	Middlebrook 7H9 Broth		0/10	
	Kirchner's Medium		0/10	

MRID Organism	Subculture Medium	Lot #	No. Exhibiting Growth / Total No. Carriers Tested	Carrier Population (CFU/ Carrier)
10 Minute Exposure Time				
500061-02 *Mycobacterium bovis* (BCG)	Modified Proskauer-Beck Broth	50812Z4	0/10	7.5×10^4
	Middlebrook 7H9 Broth		0/10	
	Kirchner's Medium		0/10	

V CONCLUSIONS

The submitted efficacy data **support** the dilutable product as a disinfectant against the following mycobacterium on hard, non-porous surfaces at a dilution of 1:34 (1-part disinfectant + 34 parts diluent) diluted in 400 ppm hard water with a 5% organic soil load for a 10-minute contact time at room temperature:

Mycobacterium bovis (BCG) 500061-01, -02

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

VI RECOMMENDATIONS

The label claims that a 1:34 dilution in 400 ppm hard water of the product, Maguard 5626, is an effective disinfectant against the following *Mycobacterium* on hard, non-porous non-food contact surfaces for a 10-minute contact time in the presence of 5% serum load:

Mycobacterium bovis (BCG)

This claim is acceptable as it is supported by the submitted data.

LABEL COMMENTS:

- Page 1; Top of page, change "Food Contact Sanitizer" to read "Food-Contact Surface Sanitizer."
- Page 2; Under TUBERCULOCIDAL, remove "(Tb)" from organism strain designation and anywhere else this appears on label.
- Page 6; Revise the "{SURFACES}" heading to include a reference to "Hard, Non-porous" surfaces
- Page 14; Under SANITIZING, revise the subheading "FOOD-CONTACT {and tobacco processing equipment..." to read "FOOD-CONTACT SURFACE {and tobacco processing equip..."
- Page 20; Under the heading for AGRICULTURAL OR HORTICULTURAL USES, indicate that the uses in this section are for "non-public health organisms."

Note to PM: Page 19 of label contains fogging use directions.